genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli.*

(3) *Limitations.* The drug is administered intramuscularly or subcutaneously. Treat dogs with skin and soft tissue infections for a minimum of 7 days and those with genitourinary infections for 7 to 21 days or until culture is negative and asymptomatic. If no response is observed after 3 days of treatment, therapy should be discontinued and the case reevaluated. Maximum duration of therapy should not exceed 30 days. Systemic aminoglycoside therapy is contraindicated in dogs with seriously impaired renal function. Not for use in breeding dogs as reproductive studies have not been conducted. Use with extreme caution in dogs in which hearing acuity is required for functioning. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 11816, Apr. 13, 1987; 52 FR 15412, Apr. 28, 1987, as amended at 53 FR 27851, July 25, 1988]

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use dosage may be continued by oral administration of tablets.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988

§ 522.82 Aminopropazine fumarate sterile solution injection.

(a) *Specifications.* Each milliliter of aminopropazine fumarate sterile aqueous solution, veterinary, contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis in cats and dogs and in colic spasms in horses.[1]

(2) It is administered intramuscularly or intravenously to dogs and cats at a level of 1 to 2 milligrams per pound of body weight. It is administered intramuscularly or intravenously to horses at a level of 0.25 milligrams per pound of body weight. Dosage can be repeated every 12 hours, as indicated.[1]

(3) Not for use in animals intended for food purposes.[1]

(4) For use only by or on the order of a licensed veterinarian.[1]

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996]

§ 522.88 Sterile amoxicillin trihydrate for suspension.

(a) (1) *Specifications.* Each vial contains 3 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

a concentration of 100 or 250 milligrams per milliliter for use as in paragraph (d) of this section.

(2) Each vial contains 25 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 250 milligrams per milliliter for use as in paragraph (e).

(b) *Sponsor.* See 000069 in §510.600(c) of this chapter.

(c) *Related tolerance.* See §556.38 of this chapter.

(d) *Conditions of use in dogs and cats*—(1) *Amount.* 5 milligrams per pound of body weight daily.

(2) *Indications for use*—(i) *Dogs.* Treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli,* and *Proteus mirabilis*; genitourinary infections (cystitis) due to *S. aureus, Streptococcus* spp., *E. coli,* and *P. mirabilis*; gastrointestinal infections (bacterial gastroenteritis) due to *S. aureus, Streptococcus* spp., *E. coli,* and *P. mirabilis*; bacterial dermatitis due to *S. aureus, Streptococcus* spp., and *P. mirabilis*; soft tissue infections (abscesses, lacerations, and wounds), due to *S. aureus, Streptococcus* spp., *E. coli,* and *P. mirabilis.*

(ii) *Cats.* Treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *S. aureus, Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli, Pasteurella* spp., and *P. mirabilis*; genitourinary infections (cystitis) due to *S. aureus, Streptococcus* spp., *E. coli, P. mirabilis,* and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli, Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus, Staphylococcus* spp., *Streptococcus* spp., *E. coli,* and *Pasteurella multocida.*

(3) *Limitations.* For use in dogs and cats only. Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 hours after the animal has become afebrile or asymptomatic. If no improvement is seen within 5 days, review the diagnosis and change therapy. As with all antibiotics, appropriate in vitro culturing susceptibility testing of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Condition of use. Cattle*—(1) *Amount.* 3 to 5 milligrams per pound of body weight once a day according to the animal being treated, the severity of infection, and the animal's response.

(2) *Indications for use.*— Treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to *P. multocida, P. hemolytica, Hemophilus* spp., *Staphylococcus* spp., and *Streptococcus* spp. and acute necrotic pododermatitis (foot rot) due to *Fusobacterium necrophorum.*

(3) *Limitations.* Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Do not continue treatment beyond 5 days. Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Maximum volume per injection should not exceed 30 milliliters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37330, Aug. 18, 1992; 60 FR 55659, Nov. 2, 1995]

§522.90 Ampicillin implantation and injectible dosage forms.

§522.90a Ampicillin trihydrate sterile suspension.

(a) *Specifications.* Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams of ampicillin.

(1) *Sponsor.* See No. 053501 in §510.600(c) of this chapter.

(2) *Related tolerances.* See §556.40 of this chapter.

(3) *Conditions of use*—(i) *Calves.*

(A) *Amount.* For enteritis: 3 milligrams per pound of body weight,